APR 17 2002 K013597

I. 510(k) SUMMARY

Submitted By:

Cindy Rumple
Cook OB/GYN®
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-4891
October 30, 2001

Device

Trade Name:	Tamponade Uterine Balloon Catheter Set
Proposed Classification Name:	Instrument, Manual, Specialized, Obstetric-Gynecologic

Predicate Devices:

The Tamponade Uterine Balloon Catheter Set is substantially equivalent to predicate devices in terms of indications for use, design, and materials of construction. Predicate devices include Mentor U-Stasis Balloon manufactured by Mentor Corporation and the Balloon Uterine Stent manufactured by Cook OB/GYN®.

Device Description:

The Tamponade Uterine Balloon Catheter Set is intended for use in reducing and controlling post-partum uterine bleeding. The construction materials of the Tamponade Uterine Balloon Catheter are all silicone. Biocompatability testing has shown the materials to meet the test requirements.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program. The device will undergo packaging and sterilization procedures similar to devices currently marketed and distributed by Cook OB/GYN®. Being similar with respect to indications for use, materials, and physical construction to predicate devices, this device meets the requirements for section 510 (K) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2002

Ms. Cindy Rumple
Regulatory Affairs
Cook Ob/Gyn
1100 W. Morgan Street
SPENCER IN 47460

Re: K013597
Trade/Device Name: Tamponade Uterine Balloon Catheter Set
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: 85 KNA
Dated: March 6, 2002
Received: March 6, 2002

Dear Ms. Rumple:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K013597

Device Name: Tamponade Uterine Balloon Catheter Set

The Tamponade Uterine Balloon Catheter Set is intended to provide temporary control or reduction of post-partum uterine bleeding when conservative management is warranted. The device is one time use and is supplied sterile.
"Use of this device is intended to provide temporary control or reduction of post-partum uterine bleeding when conservative management is warranted."

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013597